

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DDM

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Certifier A. Corbin

Oral Dosage Form New Animal Drugs; Ivermectin and Praziquantel Paste

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides revised labeling for ivermectin and praziquantel oral paste used in horses for the treatment and control of various internal parasites.

DATES: This rule is effective *[insert date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Martine Hartogensis, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-7815, e-mail: *martine.hartogensis@fda.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed a supplement to NADA 141-214 for ZIMECTERIN GOLD (ivermectin 1.55 percent/praziquantel 7.75 percent) Paste for horses. This supplement amends product labeling to separate parasite life stages in the indications section, to remove the 8-week retreatment interval from the dosage and administration section, and to add a new precaution statement. The supplemental NADA is approved as of July 13, 2004, and 21 CFR 520.1198 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1198 is amended by revising paragraphs (d)(2)(i) and (d)(3) to read as follows:

§ 520.1198 Ivermectin and praziquantel paste.

* * * * *

(d) * * *

(2) * * *

(i) For treatment and control of the following parasites in horses:

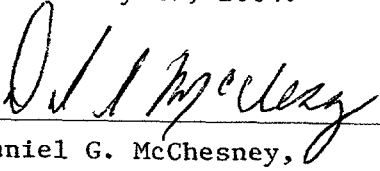
Tapeworms—*Anoplocephala perfoliata*; Large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

* * * * *

(3) *Limitations.* For oral use only. Do not use in horses intended for human consumption.

Dated: 7/27/04

July 27, 2004.



Daniel G. McChesney,
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Office of Surveillance and Compliance,
Center for Veterinary Medicine.
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